

REMARKS

Claims 92-100 are pending. Claim 92 has been amended to incorporate the limitation of claim 93. Claim 93 has been canceled. No new matter has been added. Applicant reserves the right to file a divisional application for the non-elected claims or to reinstate certain claims.

Amendment of the claims should in no way be construed as an acquiescence to any of the Examiner's rejections and was done solely to more particularly point out and distinctly claim the invention to expedite the prosecution of the application. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s).

Applicants respectfully traverse the Examiner's rejections and request reconsideration of the application in view of the amendments made above and the remarks that follow.

The Invention

Applicant's invention provides a device that optimally delivers a therapeutic agent to a tissue using ultrasound energy, without causing disruption of the tissue. The device has an ultrasound transducer to provide ultrasonic energy, an applicator to apply the therapeutic agent, and a *pressure-sensitive switch to determine the erectile state of a penis*.

Rejection of Claim 99 under 35 USC § 112 Second Paragraph

Claim 99 has been rejected under USC § 112 as second paragraph, as being indefinite for failing to positively recite "the therapeutic agent" in the claims.

Applicant thanks the Examiner for pointing out this discrepancy and has amended claim 99 to positively claim the therapeutic agent.

Rejection of Claims 92-96 and 98 under 35 USC § 102

Claims 92-96 and 98 have been rejected under 35 U.S.C. 102(b) as being anticipated by Barsotti *et al.* (US 4,791,915). In particular, the Office action asserts that:

Barsotti discloses a device 10 including an applicator 22, an ultrasound transducer including at least one oscillating element generating frequency between the range as claimed, a duty cycle greater than about 10%, *a pressure switch in the control unit 16,* (Emphasis added).

Applicant respectfully traverses the rejection. Amended claim 1 requires a transducer, and applicator and *a pressure-sensitive switch*. The pressure-sensitive switch responds to changes in pressure and is used to determine the *erectile state of a penis*. Therefore, the detumescence or loss of erection can be monitored automatically. In the event of detumescence, ultrasound energy can be applied the penis to promote renewed penile erection.

In contrast, Barsotti *et al.* simply describes an ultrasound therapy device with a transducer, a front display and control panel. Applicant respectfully disagrees with the assertion in the Office Action that the device of Barsotti *et al.* has a “pressure switch in control unit 16.” There is no such teaching in Barsotti *et al.* If the Examiner disagrees, he is respectfully requested to indicate where such a teaching occurs in Barsotti *et al.*

Thus, Barsotti *et al.* fails to teach each and every element of the claimed invention. Accordingly, the Examiner is respectfully requested to withdraw the rejection.

Rejection of Claims 92-98 under 35 USC § 102

Claims 92-98 have been rejected under 35 U.S.C. 102(e) as being anticipated by Rowe *et al.* (US 6,234,990). In particular, the Office action asserts that:

Rowe discloses various therapeutic drug delivery devices (figs. 1, 7-11) including an applicator, an ultrasound transducer including at least one oscillating element generating frequency between the range as claimed, a duty cycle greater than

about 10%, *a pressure switch* (fig. 9), ... The device can deliver several kinds of drugs. (Emphasis added).

Applicant respectfully traverses the rejection. As stated above, amended claim 1 is directed to a device with a *pressure-sensitive switch* which determines the erectile state of a penis. This pressure-sensitive switch monitors the loss of an erection and applies ultrasound energy whenever the penis becomes flaccid and there is a drop in pressure, to again promote penile erection.

In contrast, Rowe *et al.* simply describes a device that focuses or channels ultrasound energy in a narrow beam to a small area (Column 6, lines 15-19). The Office Action refers to Fig. 9 of Rowe *et al.* for support of a “pressure sensitive switch.” However, Fig. 9 only describes a device that is operated by a rechargeable battery and has a “switch 116.” (See column 10, lines 24-36, more specifically, lines 32-34). This is merely an “on/off” switch that is operated by an individual pushing the switch to an “on” or an “off” position. The switch in Rowe *et al.* is not a pressure-sensitive switch that responds automatically to changes in pressure. Moreover, the switch Rowe *et al.* cannot be used to determine the erectile state of a penis.

Thus, Rowe *et al.* fails to teach each and every element of the claimed invention. Accordingly, the Examiner is respectfully requested to withdraw the rejection.

Rejection of Claims 99 and 100 under 35 USC § 103

Claims 99 and 100 are rejected under 35 U.S.C. § 103 as being unpatentable over Rowe *et al.* in view of Neal (US 6,103,765). In particular, the Office Action asserts that:

Rowe fails to disclose the drugs cited in claim 99, and more specifically a phosphodiesterase type-5 inhibitor such as sildenafil or alprostadil. Neal teaches the use of sildenafil as a topical medicament for treating male erectile dysfunction...it would have been obvious to ...use Neal's sildenafil with Rowe's device as an alternative way of topical drug delivery....

Applicant respectfully traverses the rejection. Claims 99 and 100 depend from amended

claim 92, therefore all the limitations of claim 92 are imported into claims 99 and 100. As such, these claims require a device that has a pressure-sensitive switch. For all the reasons presented above, Rowe *et al.* does not teach or suggest a device with a pressure-sensitive switch, let alone a pressure-sensitive switch that can responds to changes in pressure, particularly changes in pressure associated with penile erection.

This deficiency is not remedied by Neal *et al.*, who merely describes methods of treating male erectile dysfunction with pharmaceutical agents. There is no teaching or suggestion in Neal *et al.* for any ultrasonic device, let alone an ultrasonic device with a pressure-sensitive switch.

Moreover, the combination of references fails to teach or suggest the claimed invention because none of the references describe a device with a pressure-sensitive switch that determines the erectile state of a penis. Thus, the skilled artisan would not be motivated to use either reference alone, or in combination to arrive at the claimed invention.

For all the foregoing reasons, the Examiner is respectfully requested to withdraw the rejections.

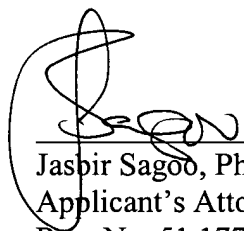
CONCLUSION

In summary, the above-identified patent application has been amended and reconsideration is respectfully requested for all the reasons set forth above. The Examiner is urged to telephone the undersigned Applicant's Attorney in the event that such communication is deemed to expedite prosecution of this matter.

Respectfully submitted,

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